

Applicant: Cy A. Stein
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REMARKS

Claims 1-7, 9-20, and 28 are pending and under examination in the subject application. By this Amendment, applicant has canceled claims 7, 14 and 28 without disclaimer or prejudice to applicant's right to pursue the subject matter of these claims in a future continuation application. In addition, applicant has added new claims 29-39. Support for new claim 29 can be found in the specification as originally filed at, *inter alia*, page 4, lines 12-18. Support for new claim 30 can be found in the specification as originally filed at, *inter alia*, page 19, lines 1-3. Support for new claim 31 can be found in the specification as originally filed at, *inter alia*, page 19, lines 4-5. Support for new claim 32 can be found in the specification as originally filed at, *inter alia*, page 19, lines 8-10. Support for new claim 33 can be found in the specification as originally filed at, *inter alia*, page 19, lines 10-11. Support for new claim 34 can be found in the specification as originally filed at, *inter alia*, page 19, lines 13-15. Support for new claim 35 can be found in the specification as originally filed at, *inter alia*, page 19, lines 15-17. Support for new claim 36 can be found in the specification as originally filed at, *inter alia*, page 20, lines 3-6. Support for new claim 37 can be found in the specification as originally filed at, *inter alia*, page 20, lines 7-8. Support for new claim 38 can be found in the specification as originally filed at, *inter alia*, page 20, line 9. Support for new claim 39 can be found in the specification at, *inter alia*, page 20, line 10. Accordingly, applicant maintains that the amendments to the claims raise no issue of new matter, and requests entry of this Amendment. After entry of this Amendment, claims 1-6, 9-13, 15-20, and 29-39 will be pending and under examination.

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Claims Rejected Under 35 U.S.C. §112 (first paragraph)

In the August 25, 2003 Office Action, the Examiner rejected claims 17-20 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for antisense-mediated inhibition of heparin expression in vitro, allegedly does not reasonably provide enablement for pharmaceutical compositions encompassing antisense-mediated inhibition activity of heparin expression in vivo. The Examiner stated that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, referring to the reasons of record set forth in the Office Action mailed August 27, 2002.

The Examiner stated that "the intended use limitations (i.e., pharmaceutical) for claimed compositions" rarely breath life and meaning into compound claims, and thus rarely provide patentable distinction in the consideration of prior art. The Examiner stated that, "In summary, the compound aspect of the claims drawn to a pharmaceutical compound may be rejected under 35 U.S.C. §102 or 35 U.S.C. §103(a), while language drawn to the pharmaceutical use of such compounds may elicit a rejection under 35 U.S.C. §112 1st paragraph enablement if the intended use is not considered to be supported by the specification." The Examiner stated that such is the present case. The Examiner stated that the rejection of the above claims is thus maintained under 35 U.S.C. §112, 1st paragraph, for lack of enablement for reasons of record.

In response, applicant traverses the Examiner's rejection. Applicant notes that the term 'pharmaceutical' does not appear in claims 17-20. Accordingly, applicant maintains that claims 17-20

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are not directed to a "pharmaceutical composition" *per se*, and are not properly rejected under 35 U.S.C. §112. Applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

Claims Rejected Under 35 U.S.C. §103(a)

The Examiner stated that claims 1-6, 9-15, 17-20, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kussie et al., in view of Pecker et al., Froehler et al., Taylor et al., and Baracchini et al. (all of record). In response, applicant traverses the Examiner's rejection. Initially, applicant notes that the references cited by the Examiner do not teach all the elements of applicant's claimed invention. Specifically, applicant notes that claim 1 is directed to a subset of oligonucleotides that are complementary to a heparanase-encoding mRNA, namely those that inhibit heparanase expression by at least 50% in T24 bladder carcinoma cells. Kussie et al., Pecker et al., Froehler et al., Taylor et al. and Barrachini et al. do not teach oligonucleotides that inhibit heparanase expression in T24 bladder carcinoma cells. In addition, applicant notes that step (c) of claim 1 is not merely functional, as previously stated by the Examiner, but characterizes a certain subset of oligonucleotides, and distinguishes these claimed oligos from those oligonucleotides which do not inhibit heparanase expression by at least 50%, such as those exemplified in the specification, see, for example, line 19, page 23 to line 14, page 26. Furthermore, the subject matter of claim 1 recites fewer elements than the procedure discussed in Taylor et al. which recites the step of determining levels of mRNA and then determining levels of protein expression (see page 565). In contrast, applicant's claimed subject matter does not recite determining levels of mRNA. The cited references in combination do not cure this

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deficiency and do not teach the method of Taylor et al. without the step of determining levels of mRNA.

In addition, applicant notes that Taylor et al. does not state whether the "bioinformatics program" used to determine potential antisense oligonucleotides is equally applicable to all targeted mRNAs. Furthermore, the "bioinformatics program" is not identified in any other way and applicant maintains that such a generic term is not enabling to one of ordinary skill in the art. There is no indication that any choice of "bioinformatics program" may be used, nor that the chosen program is suitable for determining oligonucleotides that will inhibit heparanase expression by 50%, especially in light of Taylor's own statement on page 564, right hand column, that "the best target sites are still determined empirically". Applicant notes that MPEP §2121.01 states that an enabling disclosure requires public possession, and such possession is such "if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention", and maintain that a program that is not described is not enabling. Moreover, applicant notes that the remaining references in combination with Taylor et al. do not cure these deficiencies. Accordingly, applicant maintains that the references do not suggest a reasonable expectation of success, and that the Taylor et al. reference is not enabling.

The Examiner stated that claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner stated that a sequence search performed against the oligonucleotides of SEQ ID NOS: 3, 4 and 5 indicated no anticipating prior art, and thus the oligos of the independent SEQ ID NO.S recited in claim 7

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are considered free of the art if rewritten in independent form and including all of the limitations of claim 1.

In response, applicant traverses the Examiner's objection. However, without conceding the correctness of the Examiner's position, but in order to expedite prosecution, applicant has hereinabove amended canceled claim 7 and added new claim 29 directed to the subject matter of claim 7. Applicant notes that claim 29 recites the sequences SEQ ID NOS: 3, 4 and 5, as indicated by the Examiner, in the August 25, 2003 Office Action, to be free from anticipating prior art. Accordingly, applicant respectfully requests that the Examiner allow this claim.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicant
Cooper & Dunham LLP
1185 Ave of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop AF

John P. White 2/5/04
John P. White Date
Reg. No. 28,678